

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby declare the application of: John S. PATTON, et al.)

Atty. Docket No.: 0005.15

Examiner: Gollamudi S. KISHORE

Application No.: 10/612,376

Group Art Unit: 1615

Filed: July 1, 2003

Title: METHODS AND COMPOSITIONS
FOR PULMONARY DELIVERY OF
INSULIN

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on April 12, 2006

Signed: Mina Cotter

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

In compliance with 37 CFR §§1.98 enclosed are copies of each foreign patent, each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office.

Attorney Docket No. 0005.15

04/19/2006 SFELEKE1 00000004 500348 10612376
02 FC:1464 130.00 DA

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☒ within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last)

☐ Please charge the amount of \$130 to Deposit Account 500348

☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

NEKTAR THERAPEUTICS

Dated: 12 APR 2006

By:



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Reg. No. 45,302

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Form PTO/SB/08A (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
	Applicant: John S. Patton, et al.	
	Filing Date: 07/01/2003	Group: 1615

U.S. Patent Documents

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
	1	2002/0127188	09/2002	Platz et al.			
	2	2002/0132787	09/2002	Eljamal et al.			
	3	2002/0192164	12/2002	Patton et al.			
	4	2003/0035778	02/2003	Platz et al.			
	5	2003/0068279	04/2003	Platz et al.			
	6	2003/0072718	04/2003	Platz et al.			
	7	2003/0086877	05/2003	Platz et al.			
	8	2003/0092666	05/2003	Eljamal et al.			
	9	2003/0113273	06/2003	Patton et al.			
	10	2003/0113900	06/2003	Tunnacliffe et al.			
	11	2003/0171282	09/2003	Patton			
	12	2003/0185765	10/2003	Platz et al.			
	13	2003/0198601	10/2003	Platz et al.			
	14	2003/0203036	10/2003	Gordon et al.			
	15	2003/0215512	11/2003	Foster et al.			
	16	2003/0215514	11/2003	Platz et al.			
	17	2004/0052825	03/2004	Roser et al.			
	18	2004/0096400	05/2004	Patton et al.			
	19	2004/0096401	05/2004	Patton et al.			
	20	2004/0219206	11/2004	Roser et al.			
	21	2005/0147566	07/2005	Fleming et al.			
	22	2005/0186143	08/2005	Stevenson et al.			
	23	2005/0203002	09/2005	Tzannis et al.			
	24	979,993	12/1910	O'Byrne et al.			
	25	3,555,717	01/1971	Chivers			
	26	3,619,294	11/1971	Black et al			
	27	3,632,357	01/1972	Childs			
	28	3,655,442	04/1972	Schwer, et al.			
	29	1,855,591	04/1932	Wallenstein			
	30	3,745,682	07/1973	Waldeisen			

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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Patent Documents

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	31	3,948,263	04/1976	Drake, Jr. et al.			
	32	4,102,999	07/1978	Umezawa et al.			
	33	4,127,502	11/1978	Li Mutti et al.			
	34	4,127,622	11/1978	Watanabe et al.			
	35	4,158,544	06/1979	Louderback			
	36	4,159,319	06/1979	Bachmann et al.			
	37	4,180,593	12/1979	Cohan			
	38	4,244,949	01/1981	Gupta			
	39	4,326,524	04/1982	Drake, Jr. et al.			
	40	4,327,076	04/1982	Puglia et al.			
	41	4,327,077	04/1982	Puglia et al.			
	42	4,371,557	02/1983	Oppy et al.			
	43	4,407,786	10/1983	Drake et al.			
	44	4,588,744	05/1986	McHugh			
	45	4,591,552	05/1986	Neurath			
	46	4,613,500	09/1985	Suzuki et al.			
	47	4,620,847	11/1986	Shishov et al.			
	48	4,680,027	07/1987	Parsons et al.			
	49	4,684,719	08/1987	Nishikawa et al.			
	50	4,701,417	10/1987	Portenhauser et al.			
	51	4,713,249	12/1987	Schroder et al.			
	52	4,719,762	01/1988	Osabe			
	53	4,721,709	01/1988	Seth et al.			
	54	4,739,754	04/1988	Shaner			
	55	4,758,583	07/1988	Cerami et al.			
	56	4,761,400	08/1988	Doat et al.			
	57	4,762,857	08/1988	Bollin, Jr. et al.			
	58	4,790,824	12/1988	Morrow et al.			
	59	4,793,997	12/1988	Drake et al.			
	60	4,812,444	03/1989	Mitsubishi et al.			

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U.S. Patent Documents

Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
	61	4,814,436	03/1989	Shibata et al.			
	62	4,847,079	07/1989	Kwan			
	63	4,855,326	08/1989	Fuisz			
	64	4,861,627	08/1989	Mathiowitz et al.			
	65	4,865,871	09/1989	Livesey et al.			
	66	4,866,051	09/1989	Hunt			
	67	4,883,762	11/1989	Hoskins			
	68	4,906,463	03/1990	Cleary et al.			
	69	4,988,683	01/1991	Corbiere			
	70	5,013,557	05/1991	Tai			
	71	5,026,772	06/1991	Kobayashi et al.			
	72	5,043,165	08/1991	Radhakrishnan			
	73	5,059,587	10/1991	Yamamoto			
	74	5,089,181	02/1992	Hauser			
	75	5,112,596	05/1992	Malfroy-Camine			
	76	5,112,598	05/1992	Bielsalski			
	77	5,160,745	11/1992	DeLuca et al.			
	78	5,173,298	12/1992	Meadows et al.			
	79	5,182,097	01/1993	Byron et al.			
	80	5,202,333	04/1993	Berger et al.			
	81	5,215,079	05/1993	Fine et al.			
	82	5,239,993	08/1993	Evans			
	83	5,240,712	08/1993	Smith			
	84	5,240,843	08/1993	Gibson et al.			
	85	5,240,846	08/1993	Collins et al.			
	86	5,270,048	12/1993	Drake			
	87	5,284,656	02/1994	Platz et al.			
	88	5,306,506	04/1994	Zema et al.			
	89	5,312,335	05/1994	McKinnon et al.			
	90	5,312,909	05/1994	Driessen et al.			

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Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
	91	5,342,625	08/1994	Hauer et al.			
	92	5,348,852	09/1994	Bonderman			
	93	5,366,734	11/1994	Hutchinson			
	94	5,380,473	01/1995	Bogue et la.			
	95	5,387,431	02/1995	Fuisz			
	96	5,403,861	04/1995	Goldwin et al.			
	97	5,404,871	04/1995	Goodman et al.			
	98	5,422,360	06/1995	Miyajima et al.			
	99	5,422,384	06/1995	Samuels et al.			
	100	5,425,951	06/1995	Goodrich, Jr. et al.			
	101	5,453,514	09/1995	Niigata et al.			
	102	5,512,547	04/1996	Johnson et al.			
	103	5,518,709	05/1996	Sutton et al.			
	104	5,547,696	08/1996	Sorensen			
	105	5,571,499	11/1996	Hafler et al.			
	106	5,580,859	12/1996	Felgner et al.			
	107	5,567,439	10/1996	Myers et al.			
	108	5,589,167	12/1996	Cleland et al.			
	109	5,591,453	01/1997	Ducheyne et al.			
	110	5,607,915	03/1997	Patton			
	111	5,611,344	03/1997	Bernstein et al.			
	112	5,618,786	04/1997	Roosdorp et al.			
	113	5,631,225	05/1997	Sorensen			
	114	5,621,094	04/1997	Roser et al.			
	115	5,642,728	07/1997	Andersson et al.			
	116	5,654,278	08/1997	Sorensen			
	117	5,681,746	10/1997	Bodner et al.			
	118	5,728,574	03/1998	Legg			
	119	5,705,482	01/1998	Christensen et al.			
	120	5,707,352	01/1998	Sekins			

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	121	5,733,555	03/1998	Chu			
	122	5,766,520	06/1998	Bronshtein			
	123	5,775,320	07/1998	Patton et al.			
	124	5,780,014	07/1998	Eljamal et al.			
	125	5,780,295	07/1998	Livesey et al.			
	126	5,849,700	12/1998	Sorensen et al.			
	127	5,851,453	12/1998	Hanna et al.			
	128	5,891,873	04/1999	Colaco et al.			
	129	5,928,469	07/1999	Franks et al.			
	130	5,948,411	09/1999	Koyama et al.			
	131	5,955,448	09/1999	Calaco et al.			
	132	5,792,366	10/1999	Haynes et al.			
	133	5,976,436	11/1999	Livesley et al.			
	134	5,993,783	11/1999	Eljamal et al.			
	135	5,993,805	11/1999	Sutton et al.			
	136	5,994,314	11/1999	Eljamal et al.			
	137	6,013,638	01/2000	Crystal et al.			
	138	6,034,080	03/2000	Colaco et al.			
	139	6,060,069	05/2000	Hill et al.			
	140	6,071,428	06/2000	Franks et al.			
	141	6,077,543	06/2000	Gordon et al.			
	142	6,123,924	09/2000	Mistry et al.			
	143	6,123,936	09/2000	Platz et al.			
	144	6,136,346	10/2000	Eljamal et al.			
	145	6,138,668	10/2000	Patton et al.			
	146	6,142,216	11/2000	Lannes			
	147	6,165,463	12/2000	Platz et al.			
	148	6,187,344	02/2001	Fljamel			
	149	6,190,859	02/2001	Putnak et al.			
	150	6,231,851	05/2001	Platz et al.			

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	151	6,290,991	09/2001	Roser et al.			
	152	6,258,341	07/2001	Foster et al.			
	153	6,303,581	10/2001	Pearlman			
	154	6,303,582	10/2001	Eljamel et al.			
	155	6,309,671	10/2001	Foster et al.			
	156	6,313,102	11/2001	Colaco et al.			
	157	6,331,310	12/2001	Roser et al.			
	158	6,334,182	02/2002	Sutton et al.			
	159	6,358,530	03/2002	Eljamal et al.			
	160	6,365,190	04/2002	Gordon et al.			
	161	6,372,258	04/2002	Platz et al.			
	162	6,423,334	07/2002	Brayden et al.			
	163	6,423,344	07/2002	Platz et al.			
	164	6,426,210	07/2002	Franks et al.			
	165	6,468,782	10/2002	Tunnacliffe et al.			
	166	6,479,049	11/2002	Platz et al.			
	167	6,503,411	01/2003	Franks et al.			
	168	6,509,006	01/2003	Platz et al.			
	169	6,514,496	02/2003	Platz et al.			
	170	6,518,239	02/2003	Kuo et al.			
	171	6,565,841	05/2003	Niven et al.			
	172	6,565,871	05/2003	Roser et al.			
	173	6,569,406	05/2003	Stevenson et al.			
	174	6,569,458	05/2003	Gombotz et al.			
	175	6,572,893	06/2003	Gordon et al.			
	176	6,586,006	07/2003	Roser et al.			
	177	6,589,560	07/2003	Foster et al.			
	178	6,737,045	05/2004	Patton et al.			
	179	6,592,904	07/2003	Platz et al.			
	180	6,630,169	10/2003	Bot et al.			

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Foreign Patent or Published Foreign Patent Application

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
	192	1080265	04/1960	DE				
	193	3713326	10/1987	DE				
	194	0090356	10/1983	EP				
	195	0136030	04/1985	EP				
	196	0139286	05/1985	EP				
	197	0222313	05/1987	EP				
	198	0251631	01/1988	EP				
	199	0257956	03/1988	EP				
	200	0282179	09/1988	EP				
	201	0315875	05/1989	EP				
	202	0325936	08/1989	EP				
	203	0356154	02/1990	EP				
	204	0415567	03/1991	EP				
	205	0430045	06/1991	EP				
	206	0433679	06/1991	EP				
	207	0463653	01/1992	EP				
	208	0474874	03/1992	EP				
	209	0600730	06/1994	EP				
	210	0616524	09/1994	EP				
	211	0714905	06/1996	EP				
	212	2238476	02/1975	FR				
	213	52-139789	11/1977	JP (abstract)				
	214	60-244288	12/1985	JP (abstract)				
	215	62-228272	10/1987	JP (abstract)				
	216	62-255434	11/1987	JP (abstract)				
	217	62267238	11/1987	JP (abstract)				
	218	02084401	03/1990	JP (abstract)				
	219	03264537	11/1991	JP (abstract)				
	220	06-100464	04/1994	JP (abstract)				
	221	0821036	09/1959	UK				

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	222	1381588	01/1975	UK				
	223	1533012	11/1978	UK				
	224	2187191	09/1987	UK				
	225	87/02038	04/1987	WO				
	226	88/08298	11/1988	WO				
	227	89/06976	08/1989	WO				
	228	89/09614	10/1989	WO				
	229	90/11756	10/1990	WO				
	230	91/18091	11/1991	WO				
	231	92/02133	02/1992	WO				
	232	92/18164	10/1992	WO				
	233	92/19243	11/1992	WO				
	234	93/02834	02/1993	WO (abstract)				
	235	93/10758	06/1993	WO				
	236	93/11746	06/1993	WO (abstract)				
	237	93/12240	06/1993	WO				
	238	93/13752	07/1993	WO				
	239	93/17663	09/1993	WO				
	240	93/23065	11/1993	WO				
	241	93/23110	11/1993	WO				
	242	94/07514	04/1994	WO				
	243	94/13271	06/1994	WO				
	244	94/22423	10/1994	WO				
	245	94/24263	10/1994	WO				
	246	95/01324	01/1995	WO				
	247	95/06126	03/1995	WO				
	248	95/20979	08/1995	WO				
	249	95/24183	09/1995	WO				
	250	95/31479	11/1995	WO				
	251	95/33488	12/1995	WO				

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	265	ADJEI, et al., "Pulmonary delivery of therapeutic peptides and proteins", J. Controlled Release, <u>29</u> :361-373, (1994)
	266	Advertisement for "Stop'n Grow" Manufactured by The Mentholatum Co. Ltd., East Kilbride Scotland G74 5P3
	267	AGRIMI, et al., "Amyloid, Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", Med. Hypotheses, <u>40</u> (2):113-116, (1993)
	268	AHLNECK, et al., "The Molecular Basis of Moisture Effects on the physical and Chemical Stability of Drugs in the Solid State", State Int. J. Pharm., <u>62</u> :87-95, (1990)
	269	AKERS, et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", Pharmaceutical Research, <u>12</u> (10):1457-1461, (1995)
	270	AKOH, et al., "One-stage synthesis of raffinose fatty acid polyesters", J. Food Sci., <u>52</u> (6):1570-1576, (1987)
	271	ALBERTS, et al., Molecular Biology of the Cell, 2nd ed., Garland Publishing, Inc., Ch. 2, page 58, (1989)
	272	ALDOUS, et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", Cryo-Letters, <u>16</u> :181-186, (1995)
	273	ALDRICH, et al., "Use of the spinning disk technique to produce monodisperse microspheres of human serum albumin for labeling with radioisotopes", J. Applied Radiation and Isotopes, <u>25</u> :15-18, (1974)
	274	ALLEN, et al., "Determination of the Degree of Crystallinity in Solid-Solid Equilibria", J. Pharm. Sci., <u>58</u> (10):1190-1193, (1969)
	275	ALLISON, et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", Journal of Pharmaceutical Sciences, <u>89</u> (5):682-691, (2000)
	276	ALLISON, et al., Lyophilization of Nonviral Gene Delivery Systems, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY, Ch. 18, 225-251 (Mark A. Findeis ed., Humana Press, 2001)
	277	ANCHORDOQUY, et al., Physical Stabilization of DNA Based Therapeutics, <u>6</u> (9), DDT 463-470, (May 2001)

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------------------	-------------------------

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	278	ANEKWE, et al., "Relaxation Constants as a Predictor of Protein Stabilization," Biocalorimetry: Applications of Calorimetry in the Biological Science, J. E. Ladbury and B. Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251, (1998)
	279	ARAKAWA, et al., "Protein-solvent interactions in pharmaceutical formulations", Pharm. Res., <u>8</u> (3):285-291, (1991)
	280	BANDARA, et al., "Intraarticular Expression of Biologically Active Interleukin IL-Receptor-Antagonist Protein by Ex Vivo Gene Transfer", <u>90</u> :10764-10768, (November 1993)
	281	BARNETT, "Exhubera Inhaled Insulin: A Review", Int. J. Clin. Pract., <u>58</u> (4):394-401, (2004)
	282	BELOPOL'SKAYA, et al., The Effect of Water as Natural Plasticizer on Thermal Properties of Denatured DNA Studied by Calorimetry 4 VESTNIK SANKT-PETERSBURGSKOGO UNIVERSITETA SERIYA pp. 16-22, abstract only, 2 pgs. (1999)
	283	BELL, et al., "Dry Powder Aerosols I: A New Powder Inhalation Device", J. Pharm. Sci., <u>60</u> (10):1559-1564, (October 1971)
	284	BIGSBEE, et al., "Solid State Liability of Insulin: Comparison of Crystalline and Amorphous Forms," Pharmaceutical Research 10(10): Abstract No. PDD 7418, page S-279, (1993)
	285	BLAKELY, et al., "Dry instant blood typing plate for bedside use," Lancet, <u>336</u> :854-855, (1990)
	286	BÖGELEIN, et al., "Influence of Amorphous Mannitol on Powder Properties of Spray Dried Trehalose/Dextran Mixtures", [on-line] [retrieved September 2005] Retrieved from the Internet <URL: http://www.pharmtech.unierlangen.de/APV_03_abs/bogelein.pdf > 2 pages (2003)
	287	BOOTSMA, et al., "β-Cyclodextrin as an Excipient in Solid Oral Dosage Forms: In Vitro and In Vivo Evaluation of Spray-Dried Diazepam-β-Cyclodextrin Products," International Journal of Pharmaceutics, <u>51</u> :213-223, (1989)
	288	BOSQUILLON, et al., "Aerosolization Properties, Surface Composition and Physical State of Spray-Dried Protein Powders", Journal of Controlled Release, <u>99</u> :357-367, (2004)

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08B (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	289	BRANCA, et al., "Deconstructing effect of trehalose on the tetrahedral network of water: a Raman and neutron diffraction comparison", Physica A, <u>304</u> :314-318, (2002)
	290	BRANCHU, et al. "The Effect of Cyclodextrins on Monomeric Protein Unfolding", Biocalorimetry: Applications of Calorimetry in the Biological Science, J. E. Ladbury and B.Z. Chowdhry (eds.), John Wiley & Sons, Ltd., pp. 297-301, (1998)
	291	BRANCHU, et al., "Hydroxypropyl- β -Cyclodextrin Inhibits Spray-Drying-Induced Inactivation of (β -Galactosidase", Journal of Pharmaceutical Sciences, <u>88</u> (9):905-911, (1999)
	292	BRANGE, et al., "Chemical Stability of Insulin. I. Hydrolytic Degradation During Storage of Pharmaceutical Preparations," Pharmaceutical Research, <u>9</u> (6):715-726, (1992)
	293	BREITENBACH, "Melt Extrusion: From Process to Drug Delivery Technology", European Journal of Pharmaceutics and Biopharmaceutics, <u>54</u> :107-117, (2002)
	294	BROADHEAD, et al., "The Spray Drying of Pharmaceuticals", Drug Development and Industrial Pharmacy, <u>18</u> (11 & 12):1169-1206, (1992)
	295	BROADHEAD, et al., "The Effect of process and Formulation Variables on the properties of Spray-dried β -Galactosidase", J. Pharm. Pharmacol., <u>46</u> :458-467, (1994)
	296	BROWN, "A Therapeutic Panorama of the Spongiform Encephalopathies", Antiviral Chem. Chemother., <u>1</u> (2):75-83, (1990)
	297	BUDAVARI, et al., The Merck Index, ONR-57, 12th Edition (1996)
	298	BUITINK, et al., High Critical Temperature above Tg May Contribute to the Stability of Biological Systems: BIOPHYSICAL JOURNAL 79, pp. 1119-1128, (August 2000)
	299	BURVALL, et al., "Storage of Lactose-Hydrolysed Dried Milk: Effect of Water Activity on the Protein Nutritional Value", Journal of Dairy Research, <u>45</u> :381-389, (1978)
	300	BYRON, et al., Drug Carrier Selection - Important Physicochemical Characteristics RESPIRATORY DRUG DELIVERY, 5th Edition, Interpharm Press, pp. 103-113, (1996)

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08B (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	301	BYRSTROM, et al., "Microcalorimetry – A Novel Technique for characterization of Powders", Respiratory Drug Delivery IV, Programs and Proceedings, edited by Byron, Dalby and Farr., pp. 297-302, (1994)
	302	CARPENTER, et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice", Pharmaceutical Res., <u>14</u> (8):969-975, (1997)
	303	CASSELYN, et al., Time-Resolved Scattering Investigations of Brome Mosaic Virus Microcrystals Appearance D58 ACTA CRYST., pp. 1568-1570, (2002)
	304	CAUGHEY, et al., "Sulfated Polyanion Inhibition of Scrapie-Associated PrP Accumulation in Cultured Cells", J. Virol., <u>67</u> (2):643-650, (1993)
	305	CHAN, et al., "Formulation of Vaccine Adjuvant Muramyl dipeptides (MDP). 1. Characterization of Amorphous and Crystalline Forms of a Muramyl dipeptide Analogue", Pharmaceutical Research, <u>5</u> (8):523-527, (1988)
	306	CHAN, et al., "Solid State Characterization of Spray-Dried Powders of Recombinant Human Deoxyribonuclease (RhDNase)", Journal of Pharmaceutical Sciences, <u>87</u> (5):647-654, (1998)
	307	CHAN, et al., "Physical Stability of Salmon Calcitonin Spray-Dried Powders for Inhalation" Journal of Pharmaceutical Sciences, <u>93</u> (3):792-804, (2004)
	308	CHAVAN, et al., "Effect of Particle Size and Rise in Simulated Inspiratory Flow Rate on Device Emptying in a Dry Powder Inhaler System", [on-line] [retrieved 01/07/2005] Retrieved from the Internet <URL: http://www.aapspharmsci.org/abstracts/AM_1999/1001.htm > 1 page (1999)
	309	CHAVAN, et al., "Effect of Rise in Simulated Inspiratory Flow Rate and Carrier Particle Size on Powder Emptying From Dry Powder Inhalers", AAPS Pharmsci 2000; 2(2) article 10 [on-line] Retrieved from the Internet < URL: http://www.pharmsci.org > 7 pages (2000)
	310	CHAVAN, et al., "Novel System to Investigate the Effects of Inhaled Volume and Rates of Rise in Simulated Inspiratory Air Flow on Fine Particle Output From a Dry Powder Inhaler", AAPS Pharmsci 2002; 4(2) article 6 [on-line] Retrieved from the Internet < URL: http://www.aapspharmsci.org > 6 pages (2002)
	311	CHAWLA, et al., "Production of Spray Dried Salbutamol Sulphate for Use in Dry Powder Aerosol Formulation", International Journal of Pharmaceutics, <u>108</u> :233-240, (1994)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	312	CHIOU, et al., "Pharmaceutical Applications of Solid Dispersion Systems", J. Pharm., <u>60</u> (9):1281-1302, (1971)
	313	CLELAND, et al, "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation and Oxidation", Critical Reviews in Therapeutic Drug Carrier Systems, <u>10</u> (4):307-377, (1993)
	314	CLINE, et al., "Predicting the Quality of Powders for Inhalation From Surface Energy and Area", Pharmaceutical Research, <u>19</u> (9):1274-1277, (2002)
	315	CLINE, et al., "Predicting the Quality of Powders for Inhalation", Respiratory Drug Delivery VIII 683-685, (2002)
	316	COLACO, et al., "Extraordinary Stability of Enzymes Dried in Trehalose: Simplified Molecular Biology", Bio/Technology, <u>10</u> :1007-1011, (1992)
	317	COLACO, et al., "Trehalose Stabilization of Biological Molecules", Biotechnol. Internat., pp. 345, 347-350, (1992)
	318	COLACO, et al., "Chapter 14: Chemistry of Protein Stabilization by Trehalose", ACS Symposium Series 567, Formulation and Delivery of Proteins and Peptides, J.L. Cleland & R. Langer, pp. 222-240, (1994)
	319	CONSIDINE, et al., Van Nostrand's Scientific Encyclopedia, 9th edition, Volume 2, Wiley-Interscience, John Wiley & Sons, Inc., Definition of Vaccines: pp. 3591-3592, (2002)
	320	COSTANTINO, et al., "Moisture-Induced Aggregation of Lyophilized Insulin", Pharmaceutical Research, <u>11</u> (1):21-29, (1994)
	321	COSTANTINO, et al., "Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody", Journal of Pharmaceutical Sciences, <u>87</u> (11):1406-1411 (1998)
	322	CRAIG, et al., "Maillard Reaction Kinetics in Model Preservation Systems in the Vicinity of the Glass Transition: Experiment and Theory", J. Agric. Food Chem., <u>49</u> (10):4706-4712, (2001)
	323	CROMMELIN, et al., "Liposomes", Chapter 3, Colloidal Drug Delivery Systems, J. Kreuter, editor: pp. 73-190, (1994)
	324	CROWE, et al. "Is Trehalose Special for Preserving Dry Biomaterials?" Biophysical Journal, <u>71</u> :2087-2093, (1996)
	325	CROWE, et al., "Interactions of Sugars with Membranes", Biochimica et Biophysica Acta, <u>947</u> :367-384, (1988)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	326	CROWE, et al., "The Role of Vitrification In Anhydrobiosis," Annu. Rev. Physiol., <u>60</u> :73-103, (1998)
	327	D'CRUZ, "Relationship Between Protein Thermal Stability and Glass Transition in Gelatin Polyol and Gelatin-Water Mixtures", PROCEEDINGS OF 2004 MEETING IFT, July 12-16, 2004, Las Vegas, NV, Session 17E, Food Chemistry: Proteins, [on-line] [retrieved 04/06/06] Retrieved from the Internet <URL: http://ift.confex.com/ift/2004/techprogram/paper_23006.htm > 17E-4 (2004)
	328	D'HONDT, "Possible Approaches to Develop Vaccines Against Hepatitis A", Vaccine, <u>10</u> (Suppl. 1):S48-S52m, (1992)
	329	DAEMEN, et al., "The Destruction of Enzymes and Bacteria During the Spray-Drying of Milk and Whey, 2. The Effect of the Drying Conditions", Neth. Milk Dairy J., <u>36</u> :211-229, (1982)
	330	DALBY, et al., "Relationship Between Particle Morphology and Drug Release Properties After Hydration of Aerosols Containing Liposome Forming Ingredients", Pharmaceutical Research, <u>5</u> (10):S-94, Abstract PD 888, (1988)
	331	DALBY, et al., "Droplet Drying and Electrostatic Collection: A Novel Alternative to Conventional Comminution Techniques", J. Biopharm. Sci., <u>3</u> (1/2):91-99, (1992)
	332	DALBY, et al., "Inhalation Therapy: Technological Milestones in Asthma Treatment", Advanced Drug Delivery, <u>55</u> :779-791, (2003)
	333	DARRINGTON, et al., "Evidence for a Common Intermediate in Insulin Deamidation and Covalent Dimer Formation: Effects of pH and Aniline Trapping in Dilute Acidic Solutions", Journal of Pharmaceutical Sciences, <u>84</u> (3):275-282, (1995)
	334	DE CARLO, et al., "Unexpected Property of Trehalose as Observed by Cryo-Electron Microscopy", Journal of Microscopy, <u>196</u> (1):40-45, (1999)
	335	Derwent English abstract for DE 3713326, published 10/29/1987, entitled "Spray dried water-dispersible granulates - prepd. from aq. concentrates contg. Active ingredient and ammonium carbonate or ammonium nitrate".
	336	Derwent English abstract for EP 315875, published 05/17/1989, entitled "Microcapsule prodn. contg. soluble protein or peptide - using mixt. Of polyhydroxy-butyric acid and polyactide-co-lycolide".

Examiner:	Date Considered:
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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	337	DOSE, et al., "Survival in Extreme Dryness and DNA-Single-Strand Breaks", <i>Advances in Space Research</i> , <u>12</u> (4): (4)221-(4)229, (1992)
	338	"Drug Absorption and Availability", <i>Modern Pharmaceutics</i> , 3rd edition, G. S. Banker et al. (eds), Marcel Dekker, Inc., pg. 145, (1996)
	339	DURING, et al., "Long-Term Behavioral Recovery in Parkinsonian Rats by an HSV Vector Expressing Tyrosine Hydroxylase", <i>Sci.</i> <u>266</u> (5189):1399-1403, (November 1994), [abstract – 1 pg.]
	340	EDWARDS, et al. "Crystallization of Pure Anhydrous Polymorphs of Carbamazepine by Solution Enhanced Dispersion With Supercritical Fluids (SEDSTM)", <i>Journal of Pharmaceutical Sciences</i> , <u>90</u> (8):1115-1124, (2001)
	341	ELEUTHERIO, et al., "Role of the Trehalose Carrier in Dehydration Resistance of <i>Saccharomyces Cerevisiae</i> ," <i>Biochimica et Biophysica Acta</i> , <u>1156</u> :263-266, (1993)
	342	ELKORDY, et al., "Integrity of Crystalline Lysozyme Exceeds that of a Spray-Dried Form", <i>International Journal of Pharmaceutics</i> , <u>247</u> :79-90, (2002)
	343	FAHY, et al., "Vitrification as an Approach to Cryopreservation", <i>Cryobiology</i> , <u>21</u> :407-426, (1984)
	344	FAKES, et al, "Moisture Sorption Behavior of Selected Bulking Agents Used in Lyophilized Products", <i>PDA J. Pharm Sci. Technol.</i> <u>54</u> (2): 144-149, Abstract only [on-line] [retrieved 09/25/05] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov . > (2000)
	345	FINAR, "§14. Trehalose, m.p. 203°C," under "Carbohydrate," <i>Organic Chemistry, Volume 2, Stereochemistry and the Chemistry of Natural Products</i> , 5th edition, Longman, page 323, (1996)
	346	FORBES, et al., "Water Vapor Sorption Studies on the Physical Stability of a Series of Spray-Dried Protein/Sugar Powders for Inhalation", <i>Journal of Pharmaceutical Sciences</i> , <u>87</u> (11):1316-1321, (1998)
	347	FRANKS, "Separation, Improved Freeze-Drying, an Analysis of the Basic Scientific Principles", <i>Process Biochemistry</i> , <u>24</u> (1): iii-vii, (1989)
	348	FRANKS, et al., "Freeze Drying: From Empiricism to Predictability", <i>Cryo-Letters</i> , <u>11</u> :93-110, (1990)
	349	FRANKS, et al., "Materials Science and the Production of Shelf-Stable Biologicals", <i>Pharm. Tech. Int.</i> , 7 pgs., (October 1991)

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08B (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	350	FRANKS, "Accelerated Stability Testing of Bioproducts: Attractions and Pitfalls", TIBTECH, 12:114-117, (1994)
	351	FRENCH, et al., "Moisture induced state changes in spray-dried trehalose/protein formulations", Pharmaceutical Res., 12(9 Suppl):S83, 8 pages, (1995)
	352	FUKUOKA, et al., "Glassy State of Pharmaceuticals. V. Relaxation During Cooling and Heating of Glass by Differential Scanning Calorimetry", Chem. Pharm. Bull., 39(8):2087-2090, (1991)
	353	GRAHAM, et al., "An in-vitro test for the duration of action of insulin suspension", J. Pharm. Pharmacol., 36:427-430, (1984), (PubMed abstract only)
	354	GREEN, et al., "The Protein-Glass Analogy: Some Insights from Homopeptide Comparisons", J. Phys. Chem., 98:13780-13790, (April 1994)
	355	GUPTA, et al., "Single Virus Particle Mass Detection Using Microresonators with Nanoscale Thickness", Applied Physics Letters, 84(11):1976-1978, (2004)
	356	HAHN, et al., "Solid Surfactant Solutions of Active Ingredients in Sugar Esters", Pharmaceutical Research, 6(11):958-960, (1989)
	357	HANCOCK, et al., "The Use of Solution Theories for Predicting Water Vapor Absorption by Amorphous Pharmaceutical Solids; A Test of the Flory-Huggins and Vrentas Models", Pharmaceutical Research, 10(9):1262-1267, (1993)
	358	HANCOCK, et al., "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solids", Pharmaceutical Research, 11(4):471-477, (1994)
	359	HANCOCK, et al., "Molecular Mobility of Amorphous Pharmaceutical Solids Below Their Glass Transition Temperatures", Pharmaceutical Research, 12(6):799-806, (1995)
	360	HANCOCK, et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", J. of Pharmaceutical Sciences, 86(1):1-12, (1997)
	361	HANCOCK, et al., "A Pragmatic Test of Simple Calorimetric Method for Determining the Fragility of Some Amorphous Pharmaceutical Materials", Pharm Res., 15(5):762-767, (1998)
	362	HANCOCK, et al., "The Effect of Temperature on Water Vapor Sorption by Some Amorphous Pharmaceutical Sugars", Pharmaceutical Development and Technology, 4(1): 125-131, (1999)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	363	HANES, et al., "Porous Dry-Powder PLGA Microspheres coated with Lung Surfactant for Systemic Insulin Delivery Via the Lung", Proc. Intl Symp. Control Rel. Bioactive Matter, <u>24</u> :57-58, (1997)
	364	HATLEY, et al., "Stabilization of Labile Materials by Amorphous Carbohydrates Glass Fragility and the Physiochemical Properties that Make Trehalose a Superior Excipient", Pharmaceutical Research <u>13</u> (9 Suppl.) PDD, 7165:S274, (1996)
	365	HEITEFUSS, et al. "The Stabilization of Extracts of Cabbage Leaf Proteins by Polyhydroxy Compounds for Electrophoretic and Immunological Studies," Archives of Biochemistry and Biophysics, <u>85</u> :200-208, (1959)
	366	HELLER, et al., Protein Formulation and Lyophilization Cycle Design: Prevention of Damage Due to Freeze-Concentration Induced Phase Separation 63 BIOTECHNOLOGY & BIOENGINEERING, pp. 166-174, (1999)
	367	HERRINGTON, et al., "Physico-Chemical Studies on Sugar Glasses. I. Rates of Crystallization," Journal of Food Technology, <u>19</u> :409-425, (1984)
	368	HEUBNER, et al., "Kurze Wissenschaftliche Mitteilungen", Klin. Wochenschrift, <u>51</u> :2342-2343, (1924)
	369	HICKEY, editor "Methods of Aerosol Particle Size Characterization", Pharmaceutical Inhalation Aerosol Technology, pp. 219-340, (1992)
	370	HICKEY, et al., "Behavior of Hygroscopic Pharmaceutical Aerosols and the Influence of Hydrophobic Additives," Pharmaceutical Research, <u>10</u> (1):1-7, (1993)
	371	HOENER, et al., "Factors Influencing Drug Absorption and Availability", Modern Pharmaceutics, Gilbert S. Banker et al., eds., Marcel Dekker Inc., Chapter 4, pp. 121-153, (1996)
	372	IBRAHIM, et al., "Spray Vaccination With an Improved F Newcastle Disease Vaccine. A Comparison of Efficacy With the B1 and La Sota Vaccines," Br. Vet. J., <u>139</u> :213-219, (1983)
	373	IGAKI, et al., "The Inhibition of the Maillard Reaction by L Lysine In-Vitro," J. Jpn. Diabetes Soc., <u>34</u> (5):403-407, (1991) including English abstract
	374	IGLESIAS et al., "Adsorption Isotherm of Amorphous Trehalose", J. Sci. food Agric., <u>75</u> :183-186, (1997)
	375	"Immunotherapy of Malignancy by in vivo Gene Transfer into Tumors', Hum. Gene Therapy, <u>3</u> (4):399-410, (August 1992), [abstract – 1 pg.]

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	376	IUPAC Compendium of Chemical Terminology, 1 st Edition, (1987)
	377	JAMEEL, et al., "Freeze Drying Properties of Some Oligonucleotides", Pharmaceutical Development and Technology, 6(2):151-157, (2001)
	378	Japanese Patent Publication H3-264537 (English translation), published 25 November 1991, entitled "Method for improving the elution properties of sparingly soluble drugs"
	379	JOVANOVIC-PETERSON, et al., "Jet-injected insulin is associated with decreased antibody production and postprandial glucose variability when compared with needle-injected insulin in gestational diabetic women," Diabetes Care, 16(11):1479-1484, (November 1993)
	380	KACHURA, "Method of Drying Lactic Acid Bacteria," Vinodelie I Vinogradarstvo SSSR 2:49-50, English Abstract only, one page (1985)
	381	KANNA, et al. "Denaturation of Fish Muscle Protein by Dehydration" Bull. Tokai Reg. Fish. Res. Lab. 77:70-76, English abstract (1974)
	382	KARMAS, et al., "Effect of Glass Transition on Rates of Nonenzymatic Browning in Food Systems", J. Agric. Food Chem., 40:873-879, (1992)
	383	KHAN, "Chemistry And New Uses Of Sucrose: How Important?" Pure & Appl. Chem., 56(7):833-844, (1984)
	384	KLEIN, et al., "High Velocity Microprojectiles For Delivering Nucleic Acids Into Living Cells," Nature, 327:70-73, (1987)
	385	LABRUDE, et al., "Protective Effect of Sucrose on Spray Drying of Oxyhemoglobin", J. Pharm. Sci., 78(3):223-229, (March 1989)
	386	LABUZA, et al., "Glass Transition Temperatures of Food Systems", [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: http://faculty.che.umn.edu/fscn/Ted_Lebuza/PDF_files/Isotherm_Folder/Tg%20compilation.pdf > pp. 1-31 (January 1992)
	387	LAI, et al., "Solid-State Chemical Stability of Proteins and Peptides", Journal of Pharmaceutical Sciences, 88(5):489-500, (1999)
	388	LAUBE, et al., 'Preliminary Study of the Efficacy of Insulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" JAMA, 269(16):2106-2109, (1993)
	389	LAUBE, et al., "Targeting Aerosol Deposition in Patients With Cystic Fibrosis, Effects of Alterations in Particle Size and Inspiratory Flow Rate", Chest 118(4):1069-1076 (2000)

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	390	LEDL, et al., "New Aspects of the Maillard Reaction in Foods and in the Human Body," Ang. Chem, Int. Ed. Engl., <u>29</u> :565-594, (June 1990)
	391	LEE, Developments in Food Carbohydrate - 2nd edition Applied Science Publishers, London, Table of Contents, 4 pages, (1980)
	392	LEE, " Spray Drying of Proteins," Chapter 6, Rational Design of Stable Protein Formulations, Theory and Practice, J. F. Carpenter & M. Manning, pp. 135-158, (2002)
	393	LEHNINGER, Albert L. The Molecular Basis of Cell Structure and Function BIOCHEMISTRY, Chapter 31, 859-890 (Worth Publishers Inc., 2nd edition, 1975)
	394	LESLIE, et al., "Trehalose and sucrose protect both membranes and proteins in intact bacteria during drying", Appl. Env. Microbiol., <u>61</u> (10):3592-3597, (1995)
	395	LEUNER, et al. "Improving Drug Solubility for Oral Delivery Using Solid Dispersions", European Journal of Pharmaceutics and Biopharmaceutics, <u>50</u> :47-60, (2000)
	396	LEVINE, et al., "Water as a plasticizer: physico-chemical aspects of low-moisture polymeric systems", in <u>Water Science Reviews</u> (Franks, Ed.), Vol. 3, Water Dynamics, pp. 79-175, (1988)
	397	LEVINE, et al., "Another View of Trehalose for Drying and Stabilizing Biological materials", Bio. Pharm., pp. 36-40, (1992)
	398	LI, et al., "Realistic In Vitro Assessment of Dry Powder Inhalers", Respiratory Drug Delivery VIII, pp. 687-689, (2002)
	399	LIN, et al., "Solid Particulates of Drug- β -Cyclodextrin Inclusion Complexes Directly Prepared by a Spray-Drying Technique", International Journal of Pharmaceutics, <u>56</u> :249-259, (1989)
	400	LIU, et al., "Dynamics of Pharmaceutical Amorphous Solids: The Study of Enthalpy Relaxation by Isothermal Microcalorimetry", Journal of Pharmaceutical Sciences, <u>91</u> (8):1853-1862, (2002)
	401	LOUEY, et al., "Controlled Release Products for Respiratory Delivery", APR, 7(4):82-87 [on-line] [retrieved 09/2005] Retrieved from the Internet < URL: http://www.americanpharmaceuticalreview.com/article.aspx?article=77 > 11 pages (2004)

Examiner:	Date Considered:
------------------	-------------------------

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Form PTO/SB/08B (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	402	LOUIS, et al., "Survival Of Escherichia Coli During Drying And Storage In The Presence Of Compatible Solutes" Appl. Microbiol. Biotechnol., <u>41</u> :684-688, (1994)
	403	LUECKEL, et al., "Effects of Formulation and Process Variables on the Aggregation of Freeze-Dried Interleukin-6 (IL-6) After Lyophilization and on Storage", Pharmaceutical Development and Technology, <u>3</u> (3):337-346, (1998)
	404	MACKENZIE, "Collapse During Freeze Drying-Qualitative and Quantitative Aspects", Freeze Drying and Advanced Food Technology, edited by Goldblith, Rey and Rothmayr, pp. 277-307, (1975)
	405	MAKOWER, et al., "Equilibrium Moisture Content and Crystallization of Amorphous sucrose and Glucose", Ag. and Food Chem., <u>4</u> (1):72-77, (January 1956)
	406	MARTIN, et al., "States of Matter and Phase Equilibria", Chapter 4, Physical Pharmacy, Physical Chemical Principles in the Pharmaceutical Sciences, 3 rd Edition, pp. 62-92, (1983)
	407	Masters, K., <u>Spray Drying Handbook</u> , 5 th ed., England; Longman Scientific & Technical and John Wiley & Sons, Inc., pp. 309-352 and pp. 640-642 (1991)
	408	Masters, K., <u>Spray Drying Handbook</u> , 5 th ed., New York; Longman Scientific & Technical, John Wiley & Sons, Inc., pp. 1-9, 32-33, 67-69, 491-537, 643-662, (1991)
	409	MATSUDA, et al., "Amorphism and Physicochemical Stability of Spray Dried Frusemide," J. Pharm. Pharmacol., <u>44</u> :627-633, received November 7, 1991 (1992)
	410	MATTERN, et al., "Formulation of Proteins in Vacuum-Dried Glasses. II. Process and Storage Stability in Sugar-Free Amino Acid Systems", Pharmaceutical Development & Technology, <u>4</u> (2):199-208, (1999)
	411	MILLER, et al., "Stabilization of Lactate Dehydrogenase Following Freeze-Thawing and Vacuum-Drying in the Presence of Trehalose and Borate", Pharmaceutical Research, <u>15</u> (8):1215-1221, (1998)
	412	MOLINA, et al., "The Stability of Lyophilized Lipid/DNA Complexes During Prolonged Storage," J. Pharm. Sci. 93(9):2259-2273, abstract only, one page, [on-line] [retrieved 09/2004] Retrieved from the Internet <URL: http://www.ncbi.nlm.nih.gov >, (2004)
	413	MONNIER, et al., "Mechanisms of Protection Against Damage Mediated by the Maillard Reaction in Aging", Gerontology, <u>37</u> :152-165, (1991)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	414	MOURADIAN, et al., "Degradation of Functional Integrity During Long-Term Storage of a Freeze-Dried Biological Membrane", Cryobiology, <u>22</u> : 119-127, (1985)
	415	MOYNIHAN, et al., "Dependence of the Glass Transition Temperature on Heating and Cooling Rate", J. Physical. Chem., <u>78</u> (26): 2673-2677, (1974)
	416	MURPHY, et al., "Chapter 19: Immunization Against Viruses", Fields of Virology, 2nd Edition, Volume 1, Raven Press, pp. 469-502, (1990)
	417	MURPHY, et al., Fields Virology, Volume 1, Chapter 16, Immunization Against Virus Disease, 467, at page 468, first full paragraph, first column, lines 26-33 (Bernard N. Fields et al. eds., Lippincott-Raven Publishers, 3rd ed. 1996)
	418	NABEL, et al., "Immunotherapy of Malignancy by In Vivo Gene Transfer Into Tumors," Hum. Gene. Ther. 3(4): 399-410 (August 1992) Abstract only [on-line] [retrieved 04/07/06] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstr >
	419	NABEL, et al., "Direct Gene Transfer with DNA-Liposome Complexes in Melanoma: Expression, Biologic Activity, and Lack of Toxicity in Human", Proc. Nat'l. Acad. Sci., USA, <u>90</u> :11307-11311, (December 1993)
	420	NAINI, et al., "Particles for Inhalation Produced by Spray Drying and Electrostatic Precipitation of Different Protein-Sugar Solutions", Respiratory Drug Delivery V, pp. 382-384, (1996)
	421	NAINI, et al., "Physicochemical Stability of Crystalline Sugars and Their Spray-Dried Forms: Dependence Upon Relative Humidity and Suitability for Use in Powder Inhalers", Drug Development and Industrial Pharmacy, <u>24</u> (10):895-909, (1998)
	422	NATARAJAN, Crystallization Conditions for VIPER Entries [on-line] [retrieved 11/04/04] Retrieved from the Internet <URL: http://www.xtal.tsinghua.edu.cn/research/groups/web/material/Virus%20Crystallization%20Page.htm > 5 pages (last updated Jan. 3, 2002)
	423	NEWMAN, et al., "Aerosol Therapy in AIDS", Lung, <u>168</u> (Suppl.):685-691, (1990)
	424	NIVEN, "Delivery of Biotherapeutics by Inhalation Aerosols," Pharmaceutical Technology, pp. 72-75, 80, (July 1993)
	425	NIVEN, "Delivery of Biotherapeutics by Inhalation Aerosol," Critical Reviews in Therapeutic Drug Carrier Systems, <u>12</u> (2&3):151-231, (1995)

Examiner:	Date Considered:
------------------	-------------------------

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	426	NORBERG, et al., "Glass Transition in DNA From Molecular Dynamics Simulation", Proc. Natl. Acad. Sci. USA, <u>93</u> :10173-10176, (1996)
	427	O'CONNOR, et al., Remington's Pharmaceutical Sciences, 18 th Edition, Chapter 88, "Powders", pp. 1615-1632, (1990)
	428	ODEGARD, et al., "Inhaled Insulin: Exubera", The Annals of Pharmacotherapy, <u>39</u> :843-853, (2005)
	429	OHTAKE, et al., "Effect of pH, Counter Ion and Phosphate Concentration on the Glass Transition Temperature of Freeze-Dried Sugar-Phosphate Mixtures", Pharmaceutica Research, <u>21</u> (9):1615-1621, (2004)
	430	OKAMOTO, et al., "Dry Powders for Pulmonary Delivery of Peptides and Proteins", Kona, <u>20</u> :71-83, (2002)
	431	OKSANEN, et al., "The Relationship between the Glass Transition Temperature and Water Vapor Absorption by Poly(Vinylpyrrolidone)," Pharmaceutical Research, <u>7</u> (6): 654-657 and errata on page 974, (1990)
	432	OKUMURA, et al., "Intratracheal Delivery of Calcitonin Dry Powder in Rats and Human Volunteers," S.T.P. Pharmaceutical Sciences, <u>4</u> (1):5 pages, (January, February 1994)
	433	ONODERA, et al., "Glass Transition of Dehydrated Amorphous Solid", Bull. Chem. Soc. Japan, <u>41</u> (9):2222, (1968)
	434	OWENS, et al., "Alternative Routes of Insulin Delivery," Diabetic Medicine, <u>20</u> :886-898, (2003)
	435	PALMER, et al. "X-Ray Diffractometer and Microscopic Investigation of Crystallization of Amorphous Sucrose," Agricultural and Food Chemistry, <u>4</u> (1):77-81, (January 1956)
	436	PARKS, "Studies on Glass. II The Transition Between the Glassy and Liquid States in the Case of Glucose", Journal of Physical Chemistry, Vol. 31, pp. 1366-1379, (1927)
	437	PATEL, et al., "Degradation Kinetics of High Molecular Weight Poly(L Lactide) Microspheres and Release Mechanism of Lipid: DNA Complexes", Journal of Pharmaceutical Sciences, <u>93</u> (10):2573-2584, (2004)
	438	PATTON, "Alternatives to injections: Pulmonary delivery of peptides and proteins", Chapter 16 in <u>Therapeutic Proteins, Pharmacokinetics and Pharmacodynamics</u> , (KING, et al., Eds.), pp. 329-347, (1993)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	439	PEARLMAN, et al., "Formulation Strategies for Recombinant Proteins: Human Growth Hormone and Tissue Plasminogen Activator", Therapeutic Peptides and Proteins, Formulation, Delivery and Targeting, Cold Spring Harbour, New York, pp. 23-30, (1989)
	440	PEARLMAN, et al., "Pharmaceutics of Protein Drugs", J. Pharm. Pharmacol., 44(Suppl. 1):178-185, (1992)
	441	PEKAREK, et al., "Double-walled polymer microspheres for controlled drug release", Nature, 367:258-260, (1994)
	442	"Pfizer and Inhale Therapeutic Systems Enter Pulmonary Insulin Collaboration for Dry Powder Aerosol Delivery", Health News Daily, 7(13):4-5, (1995)
	443	PHILLIPS, et al., "Size Reduction of Peptides and Proteins by Jet-Milling", Respiratory Drug Delivery VI, pp. 161-167, (1998)
	444	PIKAL, et al., "Thermal Decomposition of Amorphous β -Lactam Antibacterials", Journal of Pharmaceutical Science, 66(9):1312-1316, (September 1977)
	445	PIKAL, "Freeze-Drying of Proteins Part II: Formulation Selection", Bio. Pharm., 3(8):26-30, (October 1990)
	446	PIKAL, et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form", Pharmaceutical Research, 14(10):1379-1387, (1997)
	447	PIKAL, et al., Errata of "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," Pharmaceutical Research, 15(2):362-363, (1998)
	448	PINE, et al., "15-3 Oligosaccharides and Polysaccharides," Organic Chemistry, 4 th edition, McGraw-Hill International Book Company, page 763 (1980)
	449	PISECKY, "2. Evaporation and Membrane Filtration", Handbook of Milk Powder Manufacture, Niro A/S, Denmark, page 3, (1997)
	450	PLAUTZ, et al., "Immunotherapy of malignancy by in vivo gene transfer into tumors", Proc. Natl. acad. Sci. USA, 90:4645-4649, (May 1993), Genetics
	451	POCCHIARI, et al. "Amphotericin B: A Novel Class of Antiscrapie Drugs," J. Infect. Dis., 160(5):795-802, (November 1989)
	452	PRESTRELSKI, et al., "Separation of Freezing- and Drying-Induced Denaturation of Lyophilized Proteins Using Stress-Specific Stabilization," Archives of Biochemistry and Biophysics, 303(2):465-473, (June 1993)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	453	PRESTRELSKI, et al., "Optimization of Lyophilization Conditions for Recombinant Human Interleukin-2 by Dried-State Conformational Analysis Using Fourier-Transform Infrared Spectroscopy," <i>Pharmaceutical Research</i> , <u>12</u> (9):1250-1259, (1995)
	454	Product Insert for "Humalog® insulin Lispro injection (rDNA Origin)", Eli Lilly and Company, 8 pages (© 1996, 2000)
	455	QUAN, <i>Protein Science</i> , <u>4</u> (Suppl. 2):148, Abstract No. 490-T (1995)
	456	RAMANUJAM, et al., "Ambient-Temperature-Stable Molecular Biology Reagents," <i>Biotechniques</i> , <u>14</u> (3):470-473, (1993)
	457	Remington: The Science and Practice of Pharmacy, A. R. Gennaro, 19th edition, Mack Publishing Company, Easton, Pennsylvania 18042, pages 1517-1518
	458	RINGE, et al., "The `Glass Transition in Protein Dynamics: What it is, Why it Occurs, and How to Exploit It", <i>Biophys. Chem.</i> <u>105</u> (2-3):667-680, Abstract only, [on-line] [retrieved 11/19/04] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov > (2003)
	459	ROOS, "Phase Transitions of Mixtures of Amorphous Polysaccharides and Sugars", <i>Biotechnology Progress</i> , <u>7</u> (1):49-53, (1991)
	460	ROOS, "Melting and glass transitions of low molecular weight carbohydrates", <i>Carbohydrate Research</i> , <u>238</u> :39-48, (1993)
	461	ROSER, "Trehalose, A New Approach To Premium Dried Foods," <i>Trends in Food Sci. and Tech.</i> , pp. 166-169, (July 1991)
	462	ROSER, et al. "A Sweeter Way To Fresher Food", <i>New Scientist</i> , pp. 25-28, (May 15, 1993)
	463	SALEKI-GERHARDT, et al., "Non-Isothermal and Isothermal Crystallization of Sucrose From the Amorphous State," <i>Pharmaceutical Research</i> , <u>11</u> (8):1166-1173, (1994)
	464	SALEKI-GERHARDT, et al., "Hydration and Dehydration of Crystalline and Amorphous Forms of Raffinose," <i>Journal of Pharmaceutical Sciences</i> , <u>84</u> (3):318-323, (March 1995)
	465	SAMBROOK, et al., <i>Molecular Cloning: A Laboratory Manual</i> , 2nd. ed., "CONCENTRATING NUCLEIC ACIDS: Precipitation with Ethynol or Isopropanol", pp. E.10-E.17, Cold Spring Harbor Laboratory Press, (1989)

Examiner:	Date Considered:
------------------	-------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	466	SANCHEZ, et al., "Recombinant System for Overexpression of Cholera Toxin B Subunit In Vibrio Cholerae as a Basis for Vaccine Development" Proc. Natl. Acad. Sci. USA, <u>86</u> :481-485, (1989)
	467	SARKAR, et al., "Immunization of Mice Against Murine Mammary Tumor Virus Infection and Mammary Tumor Development", Cancer Research, <u>38</u> :1468-1472, (1978)
	468	SHAMBLIN, et al., "Enthalpy Relaxation in Binary Amorphous Mixtures Containing Sucrose", Pharmaceutical Research, <u>15</u> (12):1828-1834, (December 1998)
	469	SCHEBOR, et al., "Color Formation Due to Non-Enzymatic Browning in Amorphous, Glassy, Anhydrous, Model Systems", Food Chemistry, <u>65</u> :427:432, (1999)
	470	SCIARRA, et al., "Aerosols", Remington's Pharmaceutical Sciences, Chap. 93, 17th Ed., Mack Publishing Company, Alfonso R. Gennaro, editor, pp. 1662-1677, (1985)
	471	SEBHATU, et al., "Assessment of the Degree of Disorder in Crystalline Solids by Isothermal Microcalorimetry," International Journal of Pharmaceutics, <u>104</u> :135-144, (1994)
	472	SELLERS, et al., "Dry Powders of Stable Protein Formulations From Aqueous Solutions Prepared Using Supercritical CO ₂ -Assisted Aerosolization", Journal of Pharmaceutical Sciences, <u>90</u> (6):785-797, (2001)
	473	SERAJUDDIN, et al., "Effect of Thermal History on the Glassy State of Indapamide," J. Pharm. Pharmacol., <u>38</u> :219-220, (1986)
	474	SHALAEV, et al., "Structural Glass Transitions and Thermophysical Processes in Amorphous Carbohydrates and Their Supersaturated Solutions", J. Chem. Soc. Farady Trans., <u>91</u> (10):1511-1517, (1995)
	475	SHALAEV, et al., "How Does Residual Water Affect The Solid-State Degradation of Drugs in the Amorphous State", Journal of Pharmaceutical Sciences, <u>85</u> (11):1137-1141, (1996)
	476	SHARMA, et al., "Effect of Vacuum Drying on Protein-Mannitol Interactions: The Physical State of Mannitol and Protein Structure in the Dried State," AAPS PharmSciTech 5(1) Article 10:1-12 [on-line] [retrieved] Retrieved from the Internet <URL: http://www.aapspharmscitech.org > (2004)
	477	SINGER, et al "Thermotolerance in Saccharomyces Cerevisiae: the Yin and Yang of Trehalose", Tibtech, <u>16</u> :460-468, (1998)
Examiner:		Date Considered:

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	478	SLADE, et al., "Non-Equilibrium Behavior of Small Carbohydrate-Water Systems", Pure and Applied Chemistry, <u>60</u> (12):1841-1864, (1988)
	479	SLADE, et al., "The Glassy State Phenomenon in Food Molecules", The Glassy State in Foods, Blanshard & Lillford, editors, pp. 35-101, (1993)
	480	SOKOLOV, et al., "Glassy Dynamics in DNA: Ruled by Water of Hydration" Journa of Chemical Physics, <u>110</u> (14):7053-7057, (1999)
	481	SONNER, et al., "Spray-Freeze-Drying for Protein Powder Preparation: Particle Characterization and a Case Study With Trypsinogen Stability", Journal of Pharmaceutical Sciences, <u>91</u> (10):2122-2139, (2002)
	482	Spi PolyolsTM "What are Polyols? What do Polyols do? What are Polyols' functionality?", [on-line] [retrieved 04/06/06] Retrieved from the Internet <URL: http://www.spipolyols.com/whatarepolyols.html > one page (2003)
	483	STRIBLING, et al., "Aerosol Gene Delivery in vivo", Proc. Nat'l. Acad. Sci., <u>89</u> :11277-11281, (December 1992)
	484	STRICKLEY, et al., "Solid-State Stability of Human Insulin II. Effect of Water on Reactive Intermediate Partitioning in Lyophiles from pH 2-5 Solutions: Stabilization Against Covalent Dimer Formation", Journal of Pharmaceutical Sciences, <u>86</u> (6):645-653, (1997)
	485	STROM, et al., "Trehalose Metabolism in Escherichia coli: Stress Protection and Stress Regulation of Gene Expression", Molecular Microbiology, <u>8</u> (2):205-210, (1993)
	486	STUBBERUD, et al., "The Use of Gravimetry For The Study of the Effect of Additives on the Moisture-Induced Recrystallisation of Amorphous Lactose", International Journal of Pharmaceutics, <u>163</u> :145-156, (1998)
	487	SUKENIK, et al., "Enhancement of a Chemical Reaction Rate by Proper Orientation of Reacting Molecules in the Solid State", J. Am. Chem. Soc., <u>97</u> (18):5290-5291, (September 1975)
	488	SUSSICH, et al., "Reversible Dehydration of Trehalose and Anhydrobiosis: From Solution State to an Exotic Crystal?", Carbohydrate Research, <u>334</u> :165-176, (2001)
	489	TAKAHASHI, et al., "Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs", Nature, <u>344</u> :873-875, (April 1990)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

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Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	490	TARELLI, et al., "Additives to Biological Substances. III. The Moisture Content and Moisture Uptake of Commonly Used Carrier Agents Undergoing Processing Conditions Similar to Those Used in the Preparation of International Biological Standards," Journal of Biological Standardization, <u>15</u> :331-340, (1987)
	491	THATCHER, "Quantitation of Virus" [on-line] [retrieved 11/04/04] Retrieved from the Internet <URL: http://www.sonoma.edu/users/t/thatcher/bio1383/lab.htm > 4 pages, (last updated Jan. 5, 2002)
	492	TIMKO, et al. "Thermal Analysis Studies of Glass Dispersion Systems", Drug Devel. Ind. Pharm., <u>10</u> (3):425-451, (1984)
	493	TIMSINA, et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," International Journal of Pharmaceutics, <u>101</u> :1-13, (1994)
	494	TO, et al., "Collapse, a Structural Transition in Freeze Dried Carbohydrates", J. Fd. Technol., <u>13</u> :567-581, (1978)
	495	TOYAMA, (ed) Handbook of Natural Product for food processing, 9th Edition, Osaka, Japan, Shokuhin to Kagaku Sha, pages 384 and 495 (ISBN4-87994-048-8), (1986)
	496	URITANI, et al., "Protective Effect of Disaccharides on Restriction Endonucleases During Drying Under Vacuum," J. Biochem., <u>117</u> :774-779, (1995)
	497	ULRICH, "Biophysical Aspects of Using Liposomes as Delivery Vehicles", Bioscience Reports, <u>22</u> (2):129-150, (2002)
	498	VAIN, et al., "Development of the particle inflow gun", Plant Cell, Tissue and Organ Culture, <u>33</u> :237-246, (1993)
	499	VAVELYUK, et al., "Thermostability of DNA and Its Association with Vitrification", Tsitologiya, <u>41</u> (11):958-965, (1999)
	500	VIDGREN, et al., "In vitro and in vivo deposition of drug particles inhaled from pressurized aerosol and dry powder inhaler", Drug Devel. Indust. Pharm., <u>14</u> :2649-2665, (1983)
	501	VIDGRÉN, et al., "Comparison of Physical and Inhalation Properties of Spray-Dried and Mechanically Micronized Disodium Cromoglycate," International Journal of Pharmaceutics, <u>35</u> :139-144, (1987)

Examiner:	Date Considered:
------------------	-------------------------

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	Filing Date: 07/01/2003	Group: 1615

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	502	VROMANS, et al., "Studies on Tableting Properties of Lactose. VII. The Effect of Variations in Primary Particle Size and Percentage of Amorphous Lactose in Spray Dried Lactose Products," International Journal of Pharmaceutics, <u>35</u> :29-36, (1987)
	503	WANG, et al., eds. Stability and characterization of protein and peptide drugs, Table of Contents, 6 pages, (1993)
	504	WELSH, "The Role of Compatible Solutes In the Adaptation and Survival of Escherichia Coli," Ph.D. Thesis Submitted to Department of Biological Sciences, University of Dundee., pp. 1-262, (August 1992)
	505	WHITTIER, "Lactose and its Utilization: A review", J. Dairy Science, <u>27</u> :505-537, (July 1944)
	506	WILLIAMS, et al., "The Temperature Dependence of Relaxation Mechanisms in Amorphous Polymers and Other Glass Forming Liquids", The Journal of the American Chemical Society, <u>77</u> : 3701-3707, (1955)
	507	WOLFF, et al., "Grafting Fibroblasts Genetically Modified to Produce L-Dopa in a Rat Model of Parkinson Disease", Proc. Nat'l Acad. Sci., USA, <u>86</u> :9011-9014, (November 1989)
	508	XI, et al., "Amphotericin B Treatment Dissociates in Vivo Replication of the Scrapie Agent From PrP Accumulation", Nature, <u>356</u> :598-601, (April 1992)
	509	YORK, "Powdered Raw Materials: Characterizing Batch Uniformity", Respiratory Drug Delivery IV, Programs and Proceedings, edited by Byron, Dalby and Farr, pp. 83-91, (1994)
	510	YOSHIDA, et al., Clin. Res., "Paraprotein Immunoglobulins and Anti-RNA-Protein Autoantibodies", <u>35</u> (2), 563A, (March 1987)
	511	YOSHINARI, et al., "Moisture Induced Polymorphic Transition of Mannitol and its Morphological Transformation", International Journal of Pharmaceutics, <u>247</u> :69-77, (2002)
	512	YOSHIOKA, et al., "Crystallisation of Indomethacin From the Amorphous State Below and Above Its Glass Transition Membrane," Journal of Pharmaceutical Sciences, <u>83</u> (12):1700-1705, (December 1994)
	513	ZUBAY, G. BIOCHEMISTRY, SECOND EDITION, pages 39 & 169, Table 5-6 Major Steroid Hormones, (1988)
	514	ZUBAY, G. BIOCHEMISTRY, SECOND EDITION, pages 216-232 "Structural Properties of DNA", (1988)

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